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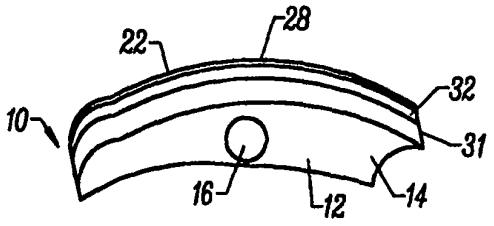
(54) Title: PATIENT MONITORING APPARATUS

(57) Abstract

An apparatus is disclosed for monitoring a physiological characteristic of a patient. The apparatus can include a patch (12) having a patch distal side (14) configured to be fixed to the skin of a patient. The patch (12) can also include a heart sensor (16) coupled with the patch (12), and positioned on the patch (12) to provide a signal indicating a state of a heart characteristic. The apparatus can also include an electronics housing (22) configured to be coupled with the patch (12). The electronic housing (22) includes receiving electronics configured to be in communication with the heart sensor (16). The receiving electronics can additionally include a processing element (44) for processing signals, and an antenna (48) for transmitting and receiving signals.



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PATIENT MONITORING APPARATUS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to a method and apparatus for monitoring a patient's physiological characteristics and more particularly to a method and apparatus for unobtrusive and long-term monitoring of a patient's physiological characteristics.

Description of the Related Art

Monitoring the physiological characteristics of particular patients can help diagnose and prevent many physical problems. For instance, patients with heart problems frequently have their heart rates monitored. When the patient's heart rate exhibits an identifiable pattern which may indicate a heart attack or other cardiac irregularity, medical professionals can be quickly summoned. The patient's life can often be saved when help is rapidly provided.

Devices which inform the patient or medical personnel of heart irregularities are commonly available for use in hospitals. Many hospital monitoring systems include electrodes which are attached to a patient via patches. The electrodes are then connected to a monitor by a wire. These wires limit the patient's freedom of movement.

U.S. Pat. No. 4,827,943 disclose a vest including numerous sensors and monitoring devices. A patient requiring long term monitoring will likely want the monitoring to be private and unnoticed by others. However, the size and

nature of the vest would make the vest obvious to a casual observer. Further, the vest could be cumbersome and could restrict the activity levels of many patients.

U.S. Pat. No. 4,829,285 discloses an alarm for sending out a distress signal. The alarm includes a tilt switch. When the tilt switch has passed a critical angle for a predetermined period of time, a signal is transmitted notifying others that the user is in need of assistance. A false alarm signal can result from the patient laying down or from other activities. Further, during a heart attack, an alarm signal may not be transmitted if the patient does not collapse.

U.S. Pat. No. 4,489,731 discloses a monitor which includes a display of heart beat data. The display of the heartbeat data is enclosed within a case in the general shape of a wristwatch which is worn on a patient's wrist. Monitors worn as a wrist watch can slip on the patient and can temporarily lose the signal they are reading. Further, these monitors can be noticed by others and accordingly do not provide the patient with the desired privacy.

An apparatus is needed for privately monitoring the physiological characteristics of a patient while maximizing the patient's freedom of movement. A need also exists for an apparatus which minimizes false results by monitoring the patient's heart in combination with other physiological characteristics. A need further exists for an apparatus which does not slip relative to the patient's skin.

SUMMARY OF THE INVENTION

An apparatus is disclosed for monitoring a physiological characteristic of a patient. The apparatus can include a patch having a patch distal side configured to be fixed to a skin surface of the patient. The patch can also include a heart sensor coupled with the patch and positioned in the patch to

provide a signal indicating a state of a heart characteristic. The apparatus can also include an electronics housing configured to be coupled with the patch. The electronics housing includes receiving electronics configured to be in communication with the heart sensor. The receiving electronics can additionally include a processing element for processing signals and an antenna for transmitting and receiving signals.

An electronics housing is disclosed for use with a patch which is configured to be fixed to a skin surface of a patient. The electronics housing includes a distal surface configured to be coupled with the patch. The electronics housing also includes receiving electronics configured to be in communication with a heart sensor included in the patch and receive from the heart sensor a signal indicating a state of a heart characteristic. The receiving electronics can additionally include a processing element for processing signals and an antenna for transmitting and receiving signals.

An apparatus is disclosed for monitoring at least one physiological characteristic of a patient. The apparatus includes a distal surface configured to be fixed to a skin surface. The apparatus includes a heart sensor positioned on the apparatus to provide a first signal indicating a state of a heart characteristic. The apparatus also includes an activity level sensor configured to provide a second signal indicating a state of a activity level of the patient. The apparatus further includes a position sensor configured to provide a third signal indicating a state of a position of the patient. Receiving electronics in the apparatus are in communication with the heart sensor, activity level sensor and position sensor. The receiving electronics can additionally include a processing element for processing signals and an antenna for transmitting and receiving signals.

An apparatus is disclosed for monitoring at least one physiological characteristic of a patient. The apparatus can include at least one physiological sensor to provide a signal indicating a state of a physiological characteristic. The apparatus also includes receiving electronics in communication with the at

least one physiological sensor. A memory resource is in communication with the receiving electronics and is configured to store signals which include information concerning the state of the physiological characteristic.

A method for monitoring a patient is disclosed. The method includes the acts of providing an apparatus for monitoring a state of a physiological characteristic; monitoring a state of the physiological characteristic; and storing information concerning the state of the physiological characteristic in the apparatus when the apparatus is out of range of a base unit.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1A is a bottom view of a dermal patch.

Figure 1B is a top view of a dermal patch.

Figure 1C is a bottom view of an electronics housing.

Figure 1D is a top view of an electronics housing.

Figure 2A illustrates the dermal patch coupled to the electronics housing.

Figure 2B illustrates the electronics housing of Figure 2A coupled with the patient.

Figure 2C is a cross section of an patch including a gripping tab for holing an electronics housing in place on the patch.

Figure 2D is a side view of a housing distal surface which is pre-formed to conform to the bodypart with which the electronics housing is coupled.

Figure 3 illustrates a remote module positioned away from the electronics housing and in communication with the electronics housing.

Figure 4 is a schematic of the electronics contained within the electronics housing.

Figure 5A illustrates a thread used to monitor a activity level sensor.

Figure 5B illustrates a thread used to monitor a heart sensor.

Figure 5C illustrates a thread used to monitor a position sensor.

Figure 5D illustrates a thread for managing data stored in a memory included in the apparatus.

Figure 6 is a schematic of a base unit which receives the signals transmitted from the electronics housing.

Figure 7 illustrates a lookup table used to identify an event.

Figure 8 is a cross section of the electronics housing.

Figure 9 is a bottom view of an electronics housing where the heart sensor is an electrode pulse sensor positioned in the electronics housing.

Figure 10 is a cross section of a position sensor for use with the apparatus.

DETAILED DESCRIPTION

The invention relates to an apparatus for monitoring a physiological characteristic of a patient. The apparatus includes an electronics housing designed to house physiological characteristic sensors such as a heart sensor, a position sensor and an activity level sensor. An embodiment of the apparatus can store the measured physiological characteristics or transmit them to a base unit. The base unit can store the physiological characteristics or transmit them to a remote processing facility for further processing. Since the transmission between the apparatus and the base unit can be wireless, the patient's freedom is movement is maximized. Further, the base unit can be positioned where the patient desires, allowing the apparatus to be used at home, at the office or at any other location away from the hospital.

One embodiment of the apparatus can be included in a system which can identify when the patient is experiencing difficulties which require medical attention. Because the apparatus can provide information regarding the condition of the patient's heart in addition to information regarding other physiological characteristics, the heart information and physiological

characteristic information can be considered in combination to reduce the number of false signals.

In operation, the electronics housing is coupled with the patient's skin in a manner which causes the sensors for the heart sensor to be substantially fixed relative to the patient's skin. Coupling the electronics hosing to the skin minimizes slippage of physiological characteristic sensors, such as a heart sensor, relative to the patient's skin. As a result, heart measurements can be taken continuously regardless of the amount of shaking and/or jarring the apparatus experiences.

In one embodiment, the surface of the apparatus to be coupled with the patient's skin can be pre-formed to the contour of the bodypart with which the apparatus is coupled. The pre-formed shape overcomes the wrinkling and bending associated with conforming two dimensional materials to three dimensional bodyparts. As a result, the comfort level of the patient is maximized allowing the apparatus to be worn long term.

One embodiment of the apparatus includes sides which are tapered to match the external shape of the bodypart with which the apparatus is coupled. As a result, the electronics housing can blend with the contours of the patient's body. This blending minimizes the chance for others to notice the presence of the apparatus when the apparatus is worn under a shirt or other article of clothing. As a result, the privacy of the patient is maximized.

An embodiment of the apparatus includes memory allowing measured physiological data to be stored within the apparatus. Further, the apparatus can include logic for detecting when the apparatus is out of range of the base unit. When the apparatus detects it is out of range of the base unit, the apparatus can store the physiological data. Accordingly, the patient can leave the range of the base unit and play sports, shop etc. and the apparatus can continue to track the patient's physiological data.

In another embodiment the stored data can be downloaded to the base unit when the apparatus is within range of the base unit. The base unit can

combine all the data it receives to compile a continuous record of the patient's physiological data over time. A physician can review the record to identify when unusual events have occurred. The physician can then review the timing of the irregularities with the patient to identify what activity the patient was doing at the time of these events. The patient can then avoid these activities or minimize stress during these activities.

The record of physiological data can also be used in conjunction with other medical information. For instance, patients with edema often use a tape measure to measure the circumference of various body parts. These measurements are used to determine how much water based swelling is present in the body part. Since water based swelling is mobile throughout the body, the circumference measurement of many body parts depends on the most recent position and activity of the patient. For instance, if the patient was standing for a while, the water will migrate toward the ankle and the ankle will exhibit an increased circumference. As a result, circumference measurements of body parts can be considered in light of the patient's physiological data record to determine whether the circumference results are due to swelling or other causes such as the recent activity level and position of the patient.

Figures 1A-1D illustrate a generalized embodiment of an apparatus 10 for monitoring a patient. As illustrated in Figure 1A, the apparatus 10 includes a dermal patch 12 with a patch distal surface 14 and a heart sensor 16. The heart sensor 16 is positioned to be responsive to a physiological characteristic of the patient's heart. The heart sensor provides a signal indicating the state of the physiological characteristic. Suitable cardiac characteristics include, but are not limited to pulse rate. As illustrated in Figure 1B, the dermal patch 12 also includes a patch proximal surface 18 and sensor contacts 20 which extend from the heart sensor 16 through the patch proximal surface 18. As illustrated in Figure 1C, the electronics housing 22 has a housing distal surface 24 and contact ports 26 which are complementary to the sensor contacts 20. As illustrated in Figure 1D, the electronics housing 22 also includes a housing

proximal surface 28 with recharge contacts 29. The electronics housing 22 is designed to hold at least one physiological sensor. Suitable physiological sensors for use with the electronics housing 22 include, but are not limited to, heart sensors, activity level sensors and position sensors.

In operation, the housing distal surface 24 is coupled to the patch proximal surface 18 as illustrated by the arrows in Figure 2A. The coupling of the dermal patch 12 and electronics housing 22 electronically couples the sensor contacts 20 and the contact ports 26. The electronics housing 22 can be held in place on the dermal patch 12 by friction between the contact ports 26 and the sensor contacts 20, by magnets, a releasable contact cement, Velcro or other releasable fastening mechanism. An adhesive which also acts as a sealant can be used to create a water proof seal between the dermal patch 12 and the electronics housing 22. A waterproof seal protects the sensor contacts 20 and allows the patient to shower with the apparatus 10 in place and minimizes any difficulties which may arise from sweat.

The electronics housing 22 can also be held in place on the dermal patch 12 as illustrated in Figure 2B. The dermal patch 12 includes a tab 30. An edge of the electronics housing is slid under the tab 30. The tab can run around the entire perimeter of the apparatus 10 or several tabs can be positioned in discrete locations on the patch. The tab 30 serves to keep the electronics housing 22 in place on the on the patch. The tab 30 can be flexible to aid in positioning the edge of the electronics housing 22 under the tab 30.

In operation, the apparatus 10 is coupled with the skin of the patient as illustrated in Figure 2C. The apparatus can be coupled with the skin on nearly any part of the patient's body which has enough surface area to accommodate the apparatus 10. For instance, the dermal patch 12 can be positioned on the patient's back as illustrated in Figure 2B. The patch edge 31 and housing edge 32 are tapered to match the contour of the patient's back. The taper can be straight as illustrated or can be curved in a convex or concave direction. As a result, the apparatus 10 can be designed to blend with the natural contour of the

patient's body so the apparatus 10 is nearly undetectable when the apparatus 10 is worn under clothing. The invisibility of the apparatus 10 protects the patient's interest in keeping the monitoring private.

As illustrated in Figure 2D, the electronics housing 22 and the dermal patch 12 can be pre-formed to the contours of the bodypart with which the electronics housing will be coupled. The pre-formed shape increases the contact area between patient's skin and the apparatus 10 and accordingly strengthens the bond between the patient's skin and the apparatus 10. The strengthened bond reduces the opportunity for the apparatus 10 to move relative to the patient's skin and accordingly reduces the patient's sensation that the electronics housing 22 is slipping. Similarly, the additional comfort provided by a conforming electronics housing 22 will help the patient adopt the monitoring apparatus as part of his/her daily life.

In one embodiment, the dermal patch 12 is disposable while the patient retains the electronics housing 22 long term. In another embodiment, the dermal patch 12 is integral with the electronics housing 22. In yet another embodiment the dermal patch 12 is eliminated by including the heart sensor 16 directly in the electronics housing 22. In this embodiment, the electronics housing 22 is attached to the skin by an adhesive which can be removed from the electronics housing 22. The adhesive can be refreshed before the electronics housing 22 is replaced on the patient's skin. Suitable adhesives include, but are not limited to hydrocolloid skin protective adhesive manufactured by 3M Corporation.

Another embodiment of the apparatus 10 includes one or more remote modules 34 as illustrated in Figure 3. Each remote module 34 can be located on the patient's body remote from the electronics housing 22. The remote module 34 can include any of the physiological sensors configured to be included in the electronics housing 22. As a result, the different physiological characteristics can be sensed from different locations. For instance, a position sensor can be located in the electronics housing 22 on the patient's back while a heart sensor

16 is positioned on the patient's wrist. The remote module 34 can communicate with the electronics housing 22 by a hard wire or by a transmitted signal. The remote module 34 can be coupled to the patient's skin by numerous means including, but not limited to, coupling the remote module 34 to a strap 36 and strapping the remote module 34 to a body part such as a wrist, directly attaching the remote module 34 to the bodypart with an adhesive and positioning an adhesive patch on the patient's skin over the remote module 34.

As shown in Figure 4, the electronics housing 22 can include the contact ports 26, a position sensor 38, an activity level sensor 40, a time/date tracking device 42, a processing element 44, a power source 46, a transmitter/receiver 48 and a memory 50. The contact ports 26, position sensor 38, activity level sensor 40, time/date tracking device 42, power source 46, transmitter/receiver 48 and memory 50 are each in electrical communication with the a processing element 44.

In operation, the position sensor 38 provides a signal indicating a position of the patient. For instance, the position sensor 38 can provide a signal indicating the vertical position of the patient, i.e. whether the patient is standing up or lying down. The same position sensor 38 can be turned ninety degrees to provide a signal indicating orientation of the patient, i.e. whether the patient is lying on his back or stomach. Two or more position sensors 38 can be used in combination to provide signals indicating both the vertical position and orientation of the patient.

In operation, the activity level sensor 40 provides a signal indicating an activity level of the patient. The time/date tracking device 42 provides a signal indicating the current time and date. The power source 46 provides the power necessary to operate the apparatus 10.

The apparatus 10 includes logic for controlling the processing element 44. The processing element 44 can use the transmitter/receiver 48 to transmit signals which are received by a base unit 60. Figures 5A-5D illustrate the process flows of the logic used by the apparatus 10

In the thread illustrated in Figure 5A, power is provided to the activity level sensor at process block 200. Many activity level sensors 40 will require a voltage in order to function. The power source 46 can be saved by turning the activity level sensor 40 off when it is not in use. Control is then passed to process block 202 where the signal provided by the activity level sensor 40 is monitored. Control is then passed to process block 204 where the signal is processed to determine a value which represents the activity level of the patient. The activity level is then added to an activity level accumulator which is a sum of the activity levels calculated over some time period. Control is then passed to process block 206 where the activity level is stored in the memory 50 along with a marker identifying the stored data as activity level data. Control is then passed to process block 208 where the activity level sensor 40 is turned off. Control is then passed to process block 210 where a time interval, T1, passes before control is returned to process block 200. Suitable T1 include, but are not limited to .1-5 seconds, .1-2 seconds and .4-.6 seconds. Process blocks 200 and 210 can be eliminated by continuously supplying power to the activity level sensor 40.

Figure 5B illustrates a thread for obtaining data from the heart sensor 16. The thread is appropriate for a heart sensor comprising electrodes positioned adjacent the patient's skin. However, the thread is easily adapted for use with other heart sensors 16. At process block 220 the signal from the heart sensor 16 is monitored. Control is then passed to process block 222 where the signal is converted to a digital signal. Control is then passed to process block 224 where the digital signal is processed. The processing can be a simple as converting the signal to a voltage and normalizing the voltage against a reference value. Control is then passed to process block 226. At process block 226 a table of previously measured voltages is edited. The table has n voltage values listed in the order they were measured. The nth voltage measurement is replaced with the presently measured voltage which becomes the first voltage measurement. All other voltage measurements are adjusted accordingly. The adjusted voltage

data stream in the table is then analyzed to find peaks which result from the potential which stimulates the heart beat. Control is then passed to process block 228 where the pulse rate is calculated. The pulse rate is calculated by dividing the number of peaks present in the table by n times T2, where T2 is the time interval between each voltage measurement. Control is then passed to process block 230 where the pulse rate is stored in the memory 50 along with a marker identifying the stored data as pulse rate data. Control then passes to process block 232 where time interval T2 passes before control is returned to process block 220. Suitable T2 include, but are not limited to, .05-.2 seconds.

In the thread illustrated in Figure 5C, power is provided to the position sensor 38 at process block 240. Many position sensors 38 will require a voltage in order to function. The power source 46 can be saved by turning the activity level sensor 40 on during operation and off when the position sensor is not in use. Control is then passed to process block 242 where the signal from the position sensor is monitored. Control is then passed to process block 244 where the signal is processed to determine the position of the patient. Control is then passed to process block 246 where the position of the patient is stored. Control is then passed to process block 248 where the position sensor 38 is turned off. Control is then passed to process block 250 where time interval T3 passes before control is returned to process block 240. Process blocks 240 and 250 can be eliminated by continuously supplying power to the position sensor 38. Suitable T3 include, but are not limited to .1-5 seconds, .1-2 seconds and .4-.6 seconds.

In process block 260 of Figure 5D, a marker indicating the time and date is stored in the memory 50. Control then passes to process block 262 where the average activity level is calculated. The activity level accumulator is divided by the number of samples used in develop the activity level accumulator. Control then passes to process block 264 where the average activity level is stored in the memory 50. Control then passes to process block 266 where the activity level accumulator is set to zero. Control then passes to process block 270 where a

retry counter is set to zero. Control then passes to process block 272 where the transmitter 48 is used to transmit the data which has been stored in the memory 50 to the base unit 60.

Control is passed from process block 272 to decision block 274. At decision block 274, a determination is made whether a signal acknowledging receipt of the transmitted data is received from the transmitter 62 in the base unit 60. When the determination is positive, control is passed to process block 276 where time interval T4 passes before control is returned to process block 260. Suitable T4 include, but are not limited to .1-20 minutes and 10-15 minutes. When the determination is negative control is passed to decision block 278.

At decision block 278 a value of one is added to the retry counter and a determination is made whether the value of the retry counter exceeds some administratively set threshold number. Suitable values for the administratively determined threshold include, but are not limited to 5. When the determination is negative control is returned to process block 272. When the determination is positive the control is passed to process block 280 where the data previously transmitted is compressed.

Control is passed from process block 280 to decision block 282. At decision block 282 a determination is made whether the capacity of the memory has been exceeded. When the determination is positive, control is returned to process block 276. When the determination is negative, control is passed to process block 284 where the compressed data is stored in the memory 50.

As illustrated in Figure 6, the base unit 60 can include a receiver/transmitter 62, a base processing element 64, a display monitor 66, a recharging cradle 68, a speaker 70, an LED 72, a modem 74, a base memory 76 and a time keeping device 77. The receiver/transmitter 62, display monitor 66, recharging cradle 68, speaker 70, LED 72, modem 74, base memory 76 and time keeping device 77 are each in electrical communication with the base processing element 64.

The base unit 60 includes logic for controlling the base processing element 64. The signals transmitted from the apparatus transmitter/receiver 48 are received by the transmitter/receiver 62. In response to the logic, the base processing element 64 can further process the received signals, store them or transmit them to another location. The base processing element 64 can display the patient's physiological characteristics to the patient on the display monitor 66.

The base processing element 64 can store the patient's physiological characteristics in the base memory 76 along with the time and date. This stored data can then be used to create a record containing at least the patient's pulse, activity and position over time. A physician can review the record to identify where cardiac irregularities or other identifiable events have occurred.

The base processing element 64 can be programmed to evaluate the physiological characteristics and identify events such as cardiac irregularities. When the base processing element 64 detects an identifiable event, such as a cardiac emergency, the patient can be notified on the display monitor 66 by flashing the LED 72 or broadcasting an enunciated announcement or alarm over the speaker 70.

The following is an example of a technique for identifying events when the physiological sensors are a pulse rate sensor 16, a position sensor 38 and an activity level sensor 40. The base processing element 64 can identify events by working from two lookup tables of physiological characteristics. One table includes data for when the patient is in the upright position and the other table includes data for when the patient is in the upright position. Figure 7 illustrates an example of a table. One column includes a range of activity levels. Corresponding to each activity level range, is an entry for the minimum acceptable heart rate and an entry for maximum acceptable heart rate.

In operation, the data received from the apparatus 10 is compared against the data in the tables. The position, activity level and pulse rate are determined for a particular moment in time. The position determines which

table is used. For instance, if the data indicate that the patient is upright, the table including data for the upright position is accessed. The activity level is then fit within the ranges in the activity level column. If the pulse rate is below the corresponding minimum acceptable heart rate, a flag signal is provided. Similarly, if the pulse rate is above the corresponding maximum acceptable heart rate, a flag signal is provided. The cycle of receiving data and comparing the received data against the tables is repeated until a threshold number of flag signals occur within a particular number of cycles. When this occurs the base unit 60 can notify the central processing facility that an event has been identified.

The maximum and minimum acceptable heart rates can be determined by studying the patient's response to certain conditions. For instance, the patient's heart rate can be studied when the patient is undergoing various activities such as sleeping, exercising and working at a desk. The maximum and minimum acceptable heart rates are then set near the limits of the normal range of pulse rates during these activities. For instance, if the upper limit on the pulse rate while sleeping is 70, 70 is the maximum acceptable heart rate corresponding to the activity level associated with sleeping. These entries are made in the prone position lookup table. Frequently, it will be unnecessary to study the patient since the maximum and minimum acceptable heart rate data can be taken from commercially available tables which correlate a patient's age weight and height with acceptable heart rate ranges.

The above logic and lookup table can be included in the apparatus 10. When the processing element 44 identifies an event, the processing element 44 cause a signal to be transmitted to the base unit 60 indicating that an event has been detected. This event detection transmission occurs regardless of whether T4 has expired. The base unit can then notify the remote processing facility and/or provide and audible or visual alarm on the display monitor 66 by flashing the LED 72 or broadcasting an enunciated announcement or alarm over the speaker 70. Similarly, the apparatus 10 can include an LED 100, a speaker, a

vibrator, a buzzer or other alarm indicator which can be used to notify the patient that an event has been identified.

The base processing element 64 can be in two way communication with a remote processing facility 78 via the modem 74. The base processing element 64 can notify the remote processing facility that is has detected an identifiable event such as fibrillation. If personnel at the remote processing facility 78 determine that the event requires medical attention, they can notify medical professionals that immediate care is required at the patient's location. The determination of the remote facility personnel can be done by placing a phone call to the patient and questioning the patient or others. Similarly, the determination can be made by analyzing physiological characteristic data provided by the base unit 60.

Personnel at the remote processing facility 78 can also use the modem 74 to download the stored patient record from the base memory 76. The downloaded patient record can then be professionally analyzed.

Similarly, personnel at the central processing facility 78 can use the modem connection to change the program used by the base processing element 64. For instance, personnel at remote processing facility can alter a variable such as T1, T2, T3 or T4. Similarly, the personnel can alter a parameter that the base processing element 64 considers before notifying the central processing facility 78.

The base unit 60 can also include a recharge cradle 68 for recharging the power source 50. The recharge cradle 68 includes recharge contacts 80 which are complementary to the recharge contacts 29 on the electronics housing 22. When the apparatus 10 is not in use, the apparatus 10 can be placed in the recharging cradle 68. This placement electronically couples the recharge contacts 80 on the recharge cradle 68 with the recharge contacts 29 on the apparatus 10. In an embodiment of the apparatus 10 including contact ports 26, the recharge contacts 29 can be eliminated by recharging the power source through the contact ports 26. In this embodiment the contact ports 26 are

coupled with the recharge contacts 80 when the apparatus 10 is positioned in the recharge cradle 68.

The base unit 60 can also include a rechargeable power source so the base unit can be portable and carried with the patient away from its normal resting place. The base unit 60 can be rested in a cradle to recharge the power source when the base unit is in its normal resting place. The base unit can also include a cellular modem so the central processing facility 78 and base unit 60 can exchange information when the base unit 60 is being carried by the patient. In another embodiment, the modem 74 includes a data port. A cellular phone can be coupled with the modem 74 via the data port.

The electronics housing 22 can be constructed as illustrated in Figure 8. The electronics are enclosed in a casing 83A designed to protect the electronics. The casing 83A is enclosed in a covering 83B which can be soft and contoured to provide a natural feel. The covering 83B can be held in place on the casing 83A by an adhesive or the covering can be shaped to enclose the casing 83A as illustrated. Suitable materials for the casing 83A include, but are not limited to, stainless steel, PVC, Nylon or other protective plastic. Suitable materials for the covering 83B include, but are not limited to Latex, silicon or another rubberized fabric. The casing 83A can be constructed to be waterproof so the patient may swim or shower with the electronics in place and sweat will not affect operation of the apparatus 10.

The electronics housing 22 can be a variety of shapes including square, rectangular and round. The housing distal surface 24 preferably has a length, width or diameter of .25-2.0 inches, more preferably from .25-1.5 inches and most preferably from .25-1.0 inches. The electronics housing 22 preferably has a maximum height of .0625-1.0 inches, more preferably .0625-.50 and most preferably .0625-.25 inches.

The patch 12 can be constructed from any material which is waterproof, pliable and compatible with skin contact. Suitable materials for the patch 12 include, but are not limited to, Latex, silicon or other rubberized fabrics.

Suitable adhesives for coupling the patch 12 with the patient's skin include, but are not limited to, hydrocolloid skin protective adhesive manufactured by 3M.

The dermal patch 12 can have a variety of geometries and dimensions. Suitable geometries include, but are not limited to, round, square and rectangular. Suitable dimensions include, but are not limited to, a perimeter with dimensions larger than the perimeter of the electronics housing, which matches the perimeter of the electronics housing or which is encompassed by the perimeter of the electronics housing.

The heart sensor 16 can be any device or combination of devices which can provide a signal indicating the condition of the patient's heart. For instance, heart sensor 16 can be an EKG sensor and a pulse sensor. Suitable pulse sensors include, but are not limited to, electrodes used to measure skin surface potential, a pressure sensor, a sonic sensor, red or infrared light transmission or reflection coupled to an infrared or red light sensor, and Doppler measurement devices.

Figure 9 illustrates an apparatus 10 where the heart sensor 16 is an electrode pulse sensor positioned in the electronics housing 22. The electrodes 82 are positioned on the housing distal surface 24 so they will contact the patient's skin when the apparatus 10 is coupled with the patient's skin. As illustrated, the electrodes 82 are positioned on opposing sides of the housing distal surface to increase the potential between the electrode. The housing distal surface 24 can include a conductive coating over the electrode contacts. When heart sensor 16 is a pressure sensor, the pressure sensor can be positioned within the electronics housing 22. The housing distal surface 24 can be sufficiently supple that the pressure sensor is responsive the pulse through the housing distal surface 24. Similarly, when the heart sensor 16 is a pressure sensor, the heart sensor 16 can be integrated into the housing distal surface 24 such that the pressure sensor directly contacts the patient's skin. Heart sensors 16 which provide an analog signal can include an A/D converter before the signal is provided to the processing element 44.

The position sensor 38 can be any of the many commercially available device which provides a signal indicating the vertical position of the patient. Figure 10 illustrates a simple embodiment of a position sensor 38 appropriate for use with the apparatus 10. The position sensor 38 includes a magnet 90, a spring 92 and a hall effect device 94. The position sensor 38 is placed so an upright patient will cause the magnet 90 to ride lower on the spring 92, thus, the hall effect device 94 will provide a different signal than if the patient were lying down and the magnet 90 rode higher on the spring 92. As a result, a relationship can be determined between the signal from the hall effect device 94 and the vertical position of the patient. The processing element 44 monitors the signal from hall effect device 94 and uses this relationship to determine the patient's position. Other suitable position sensors 38 include, but are not limited to a mercury ball in a spherical reservoir. The mercury ball completes a circuit when the patient is in one position. When the patient moves away from that position the mercury ball moves and breaks the circuit. As a result, the current through the circuit can be monitored to determine the position of the patient. Position sensors 38 which provide an analog signal can include an A/D converter before the signal is provided to the processing element 44.

The activity level sensor 40 can be any sensor which provides a signal indicating the activity level of the patient. Activity level sensors 40 typically measure forces exerted on the them. Since the activity level sensor 40 is coupled with the electronics housing 22 or is included as a remote module 34, and the electronics housing 22 or the remote module 34 can be positioned nearly anywhere on the body including the torso or limbs, the activity level sensor 40 will measure the activity level of particular bodyparts. Measured forces may be a result of acceleration or change in the direction of the body. The signal provided by the activity level sensor 40 will be a function of the activity level of the patient. When the activity level sensor 40 indicates a high level of activity, the patient is likely exercising. When the activity level sensor 40 indicates a low activity level, it is possible the patient is working at a desk or sleeping.

Suitable activity level sensors 40 include, but are not limited to, the accelerometer ADXL202 manufactured by Analog Devices. Activity level sensors 40 which provide an analog signal can include an A/D converter before the signal is provided to the processing element 44.

In the apparatus 10, suitable power sources 46 include, but are not limited to, compact lithium ion and NiCd batteries. Suitable processing elements 44 include, but are not limited to, a microprocessor such as the ARM microprocessors manufactured by any number of manufacturers. Suitable time/date tracking devices 42 include, but are not limited to common clock chips such as the DS1685 made by Dallas semi-conductor. Communications between the apparatus 10 and the base unit 60 can be in the form of an RF signals, IR signals and the like. Accordingly, suitable transmitter/receivers 48 include, but are not limited to miniaturized RF antenna. Suitable memories 42 include, but are not limited to commercially available static RAM chips.

In the base unit, suitable receiver/transmitters 62 include but are not limited to miniaturized RF antennas. Suitable base processing elements 64 include, but are not limited to, a microprocessor such as the ARM microprocessors manufactured by any number of manufacturers. Suitable display monitors 66 include, but are not limited to commonly available liquid crystal displays. Suitable modems 74 include, but are not limited to the commercially available modems commonly used with PCs. Suitable base memories 76 include, but are not limited to commercially available static RAM chips. Suitable time keeping devices 77 include, but are not limited to, common clock chips such as the DS1685 and the DS1475 manufactured by Dallas Semiconductors. The DS1475 includes memory which can serve as the memory 50 in the apparatus 10.

The invention also includes a method. A medical professional can use the invention to find activities which may trigger identifiable events. The medical professional can review a record of a patient's pulse, position and activity level over time to find identifiable events. The medical professional can

then ask the patient what he/she was doing at the time an identifiable event occurred. For instance, if a period of a dangerously low heart rate is accompanied by a low activity level, it is possible the patient is working at a desk or sleeping. If position sensor 38 indicates an upright position it is more likely he was working. Further, if the time and date indicate it was 1:00 P.M. on a Tuesday, this is even more likely. The physician can then consult with the patient to see if this was correct. If this pattern occurs regularly during this time of day, the patient can then avoid stressful activities during this time of day or take other preventative measures.

Other embodiments of the invention can include providing messages over a speaker, LED or display monitor 66 which notifies the patient power source 46 is running low or that the patient is getting out of range of base unit 60. Still other embodiments include a button on base unit 60 which cause the base processing element 64 to use modem 74 to notify the remote processing facility that an emergency situation has arisen at the location of the patient.

The foregoing description of the preferred embodiment of the invention has been for the purpose of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

CLAIMS

What is claimed is:

1. An apparatus for monitoring a physiological characteristic of a patient, comprising:

a patch having a patch distal side configured to be fixed to a skin surface of the patient;

a heart sensor coupled with the patch and positioned in the patch to provide a signal indicating a state of a heart characteristic;

an electronics housing configured to be coupled with the patch; and

receiving electronics included in the electronics housing and configured to be in communication with the heart sensor.

2. The apparatus of claim 1, wherein the heart sensor is a pulse sensor.

3. The apparatus of claim 1, further comprising:
an antenna included in the receiving electronics.

4. The apparatus of claim 1, further comprising:
a processing element included in the receiving electronics.

5. The apparatus of claim 1, further comprising:
an activity level sensor in communication with the receiving electronics.

6. The apparatus of claim 1, further comprising:
a position sensor in communication with the receiving electronics.

7. The apparatus of claim 1, further comprising:
a memory resource in communication with the receiving electronics.

8. The apparatus of claim 1, wherein the electronics housing is pre-shaped to conform to the skin surface of the patient.

9. The apparatus of claim 1, wherein the patch is pre-shaped to conform to the skin surface of the patient.

10. An electronics housing for use with a patch configured to be fixed to a skin surface, comprising:

a distal surface configured to be coupled with the patch;

receiving electronics configured to be in communication with a heart sensor included in the patch and receive from the heart sensor a signal indicating a state of a heart characteristic.

11. The apparatus of claim 10, wherein the heart sensor is a pulse sensor.

12. The apparatus of claim 10, further comprising:
an antenna included in the receiving electronics.

13. The apparatus of claim 10, further comprising:
a processing element included in the receiving electronics.

14. The apparatus of claim 10, further comprising:
an activity level sensor in communication with the receiving electronics.

15. The apparatus of claim 10, further comprising:
a position sensor in communication with the receiving electronics.

16. The apparatus of claim 10, further comprising:
a memory resource in communication with the receiving electronics.

17. The apparatus of claim 10, wherein the electronics housing is pre-shaped to conform to the skin surface.

18. An apparatus for monitoring at least one physiological characteristic of a patient, comprising:

a distal surface configured to be fixed to a skin surface of the patient;

a heart sensor positioned on the apparatus to provide a first signal indicating a state of a heart characteristic;

an activity level sensor configured to provide a second signal indicating a state of a activity level of the patient;

a position sensor configured to provide a third signal indicating a state of a position of the patient; and

receiving electronics in communication with the heart sensor, activity level sensor and position sensor.

19. The apparatus of claim 18, wherein the heart sensor is a pulse sensor.

20. The apparatus of claim 18, further comprising:

an antenna included in the receiving electronics.

21. The apparatus of claim 18, further comprising:

a processing element included in the receiving electronics for processing the first signal, the second signal and the third signal.

22. The apparatus of claim 18, further comprising:

an activity level sensor in communication with the receiving electronics.

23. The apparatus of claim 18, further comprising:

a position sensor in communication with the receiving electronics.

24. The apparatus of claim 18, further comprising:

a memory resource in communication with the receiving electronics.

25. An apparatus for monitoring at least one physiological characteristic of a patient, comprising:

at least one physiological sensor to provide a signal indicating a state of a physiological characteristic;

receiving electronics in communication with the at least one physiological sensor; and

a memory resource in communication with the receiving electronics and configured to store signals which include information concerning the state of the physiological characteristic.

26. The apparatus of claim 25, wherein the receiving electronics include logic for storing information concerning the physiological characteristic when the apparatus is out of range of a base unit.

27. The method of claim 26, further comprising:

logic for transmitting the stored information when the apparatus is within range of the base unit.

28. The apparatus of claim 25, wherein the receiving electronics include logic for transmitting a signal which includes information concerning the physiological characteristic when the apparatus is within range of a base unit.

29. The apparatus of claim 25, wherein the at least on physiological sensor is a pulse sensor.

30. The apparatus of claim 25, further comprising:

an antenna included in the receiving electronics.

31. The apparatus of claim 25, further comprising:
a processing element included in the receiving electronics.

32. The apparatus of claim 25, wherein the at least one physiological sensor is an activity level sensor.

33. The apparatus of claim 25, wherein the at least one physiological sensor is a position sensor.

34. The apparatus of claim 25, wherein the apparatus is pre-shaped to conform to the skin surface of the patient.

35. A method for monitoring a patient, comprising the acts of:
providing an apparatus for monitoring a state of a physiological characteristic;
monitoring a state of the physiological characteristic; and
storing within the apparatus information concerning the state of the physiological characteristic when the apparatus is out of range of a base unit.

36. The method of claim 35, further comprising the act of:
transmitting a signal which includes information concerning the physiological characteristic when the apparatus is within range of the base unit.

37. The method of claim 35, further comprising the act of:
transmitting the stored information when the apparatus is within range of the base unit.

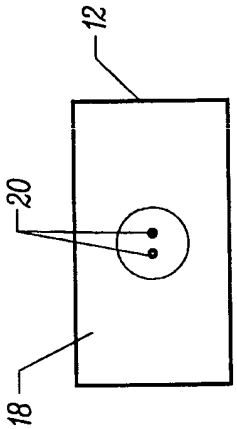

FIG. 1B

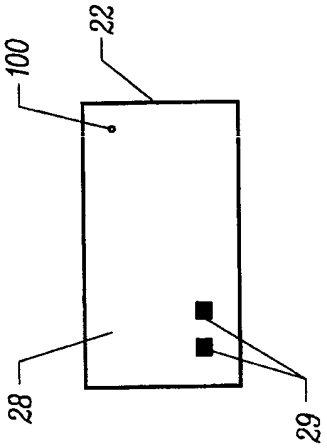

FIG. 1D

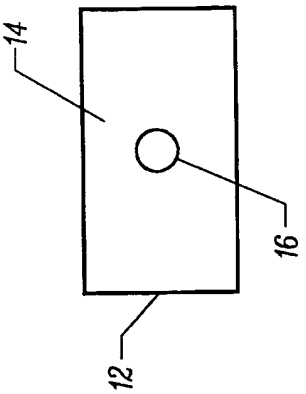

FIG. 1A

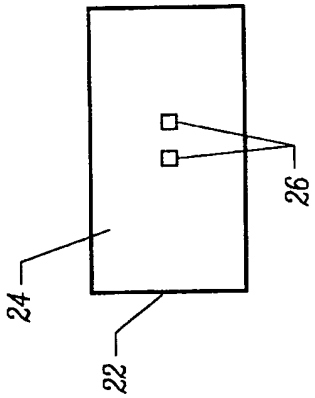

FIG. 1C

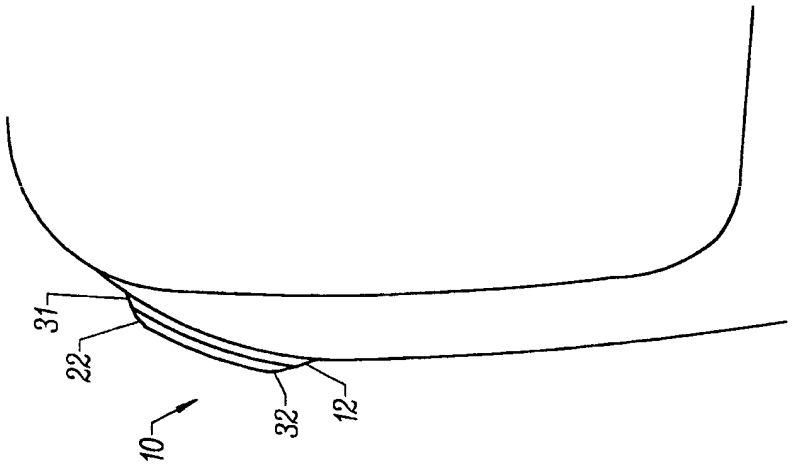

FIG. 2C

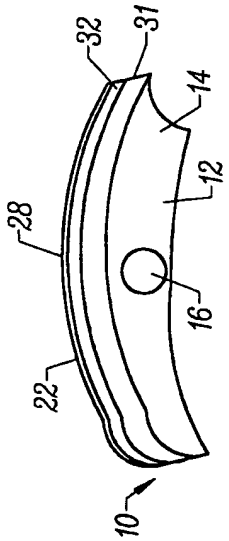

FIG. 2D

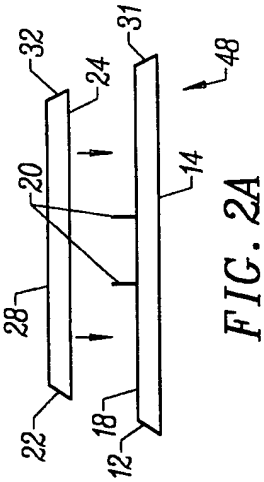

FIG. 2A

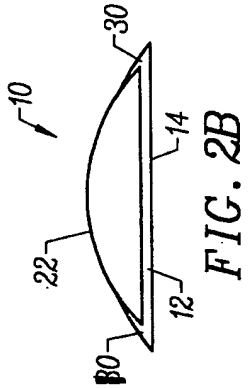

FIG. 2B

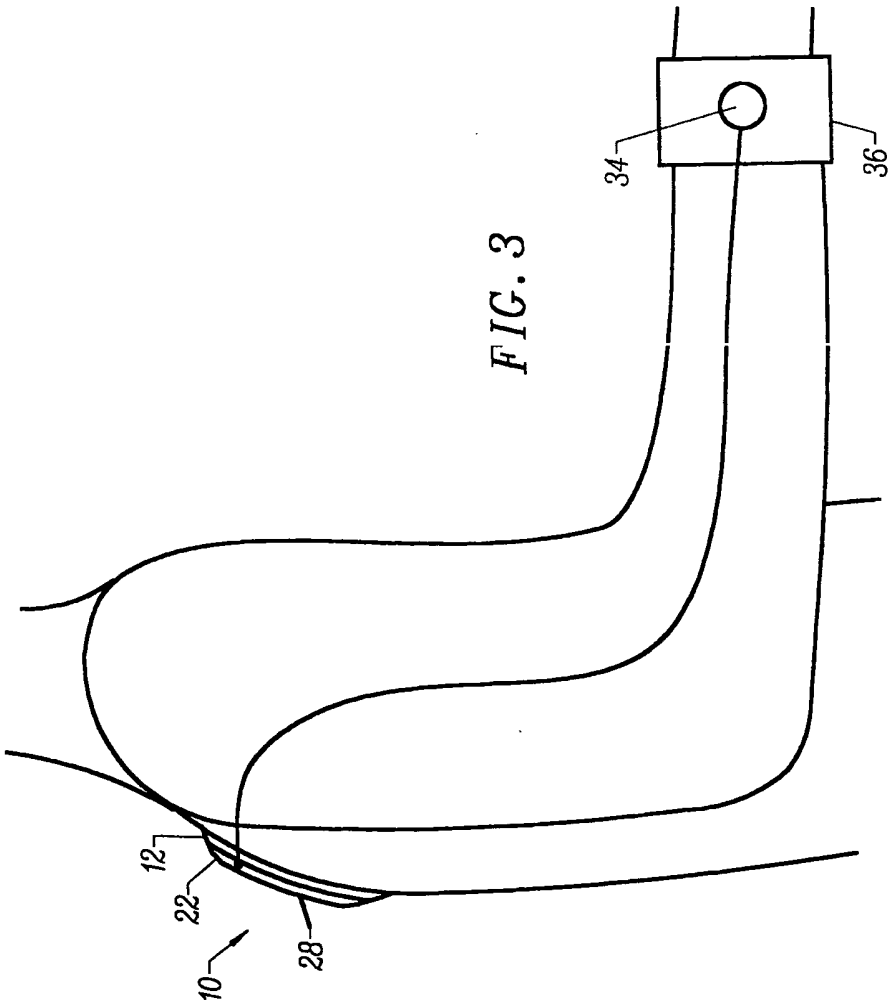

FIG. 3

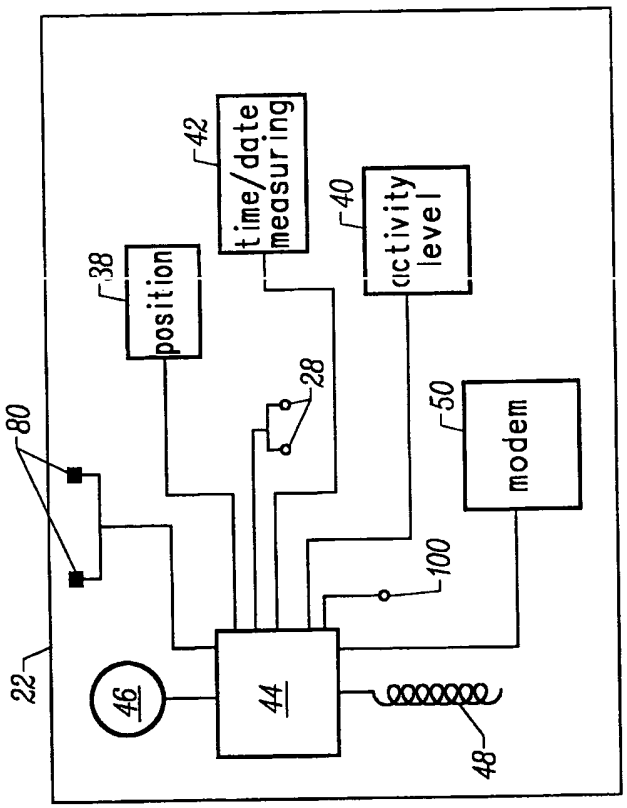
42
time/date measuring
40
activity level
38
position
28
50
modem
80
100
22
46
44
48

FIG. 4

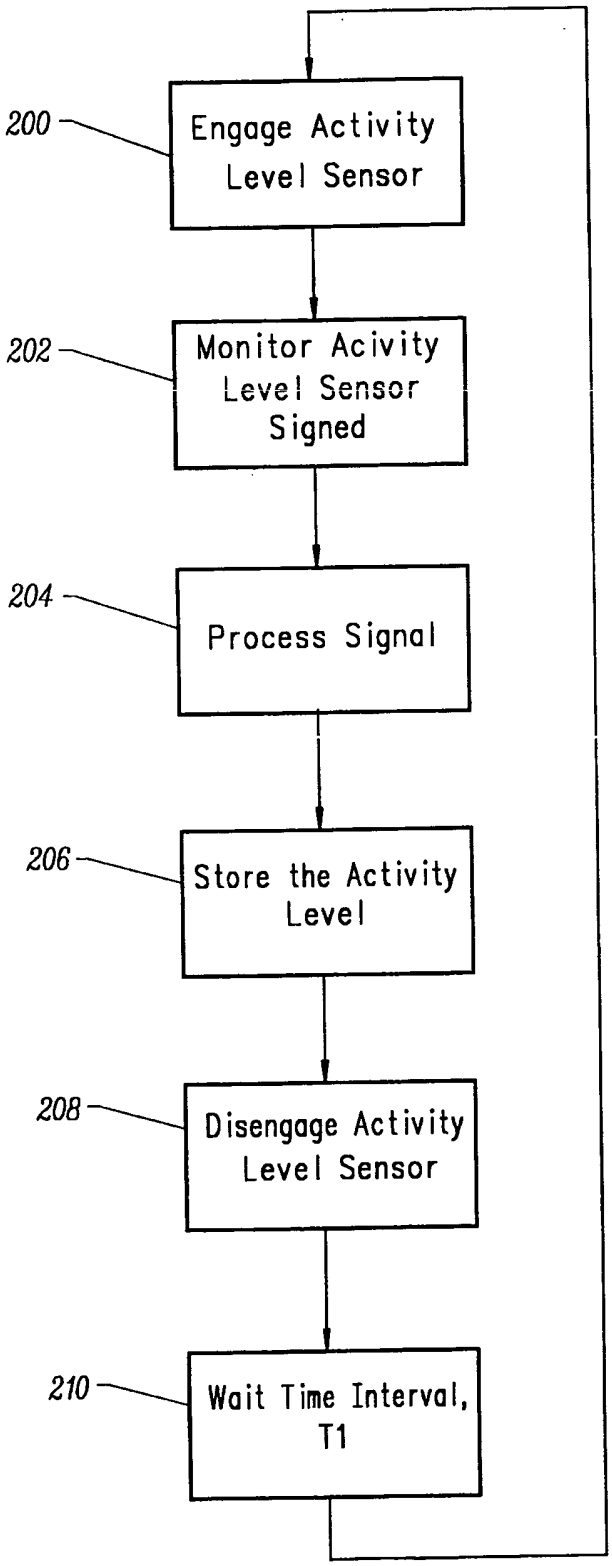
200
Engage Activity Level Sensor
202
Monitor Acivity Level Sensor Signed
204
Process Signal
206
Store the Activity Level
208
Disengage Activity Level Sensor
210
Wait Time Interval, T1

FIG. 5A

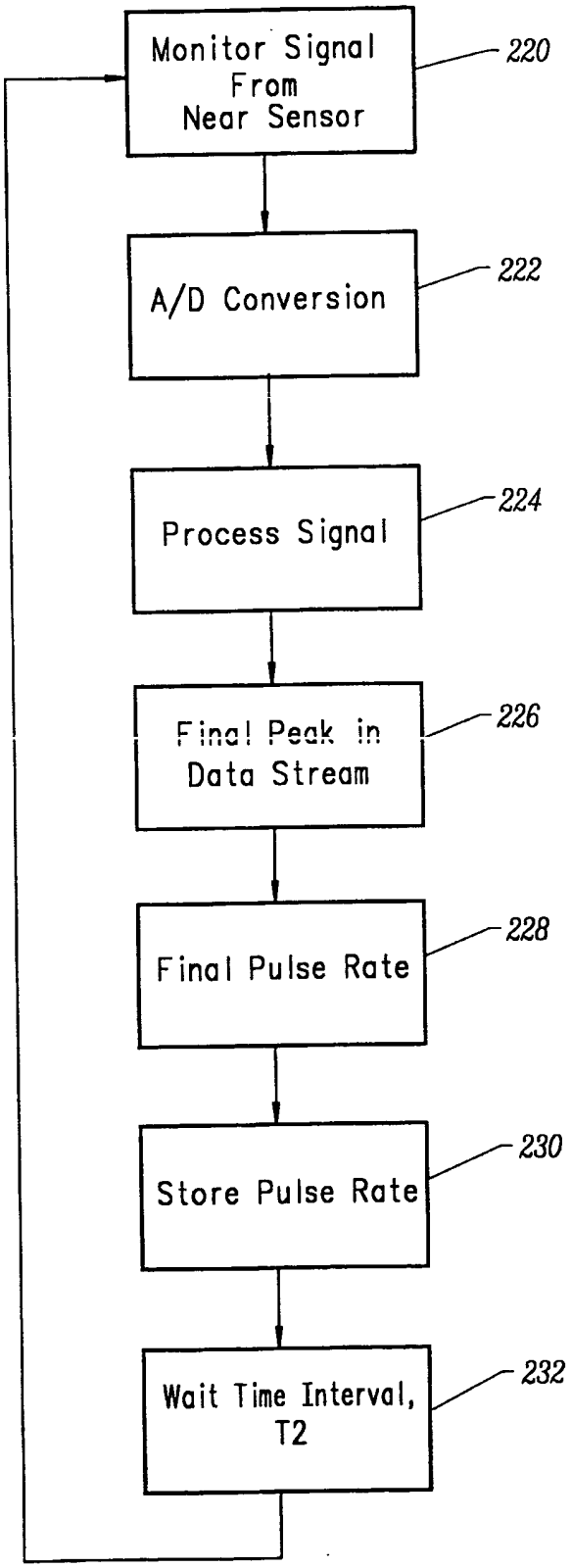
Monitor Signal From Near Sensor
220
A/D Conversion
222
Process Signal
224
Final Peak in Data Stream
226
Final Pulse Rate
228
Store Pulse Rate
230
Wait Time Interval, T2
232

FIG. 5B

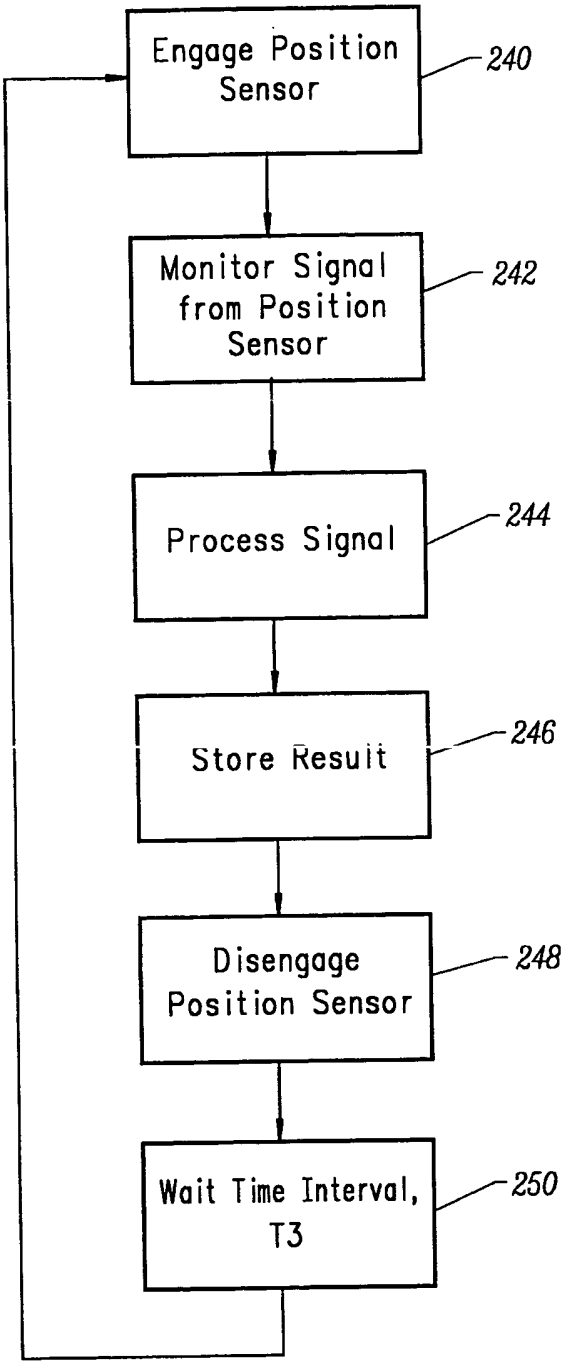
Engage Position Sensor
240
Monitor Signal from Position Sensor
242
Process Signal
244
Store Result
246
Disengage Position Sensor
248
Wait Time Interval, T3
250

FIG. 5C

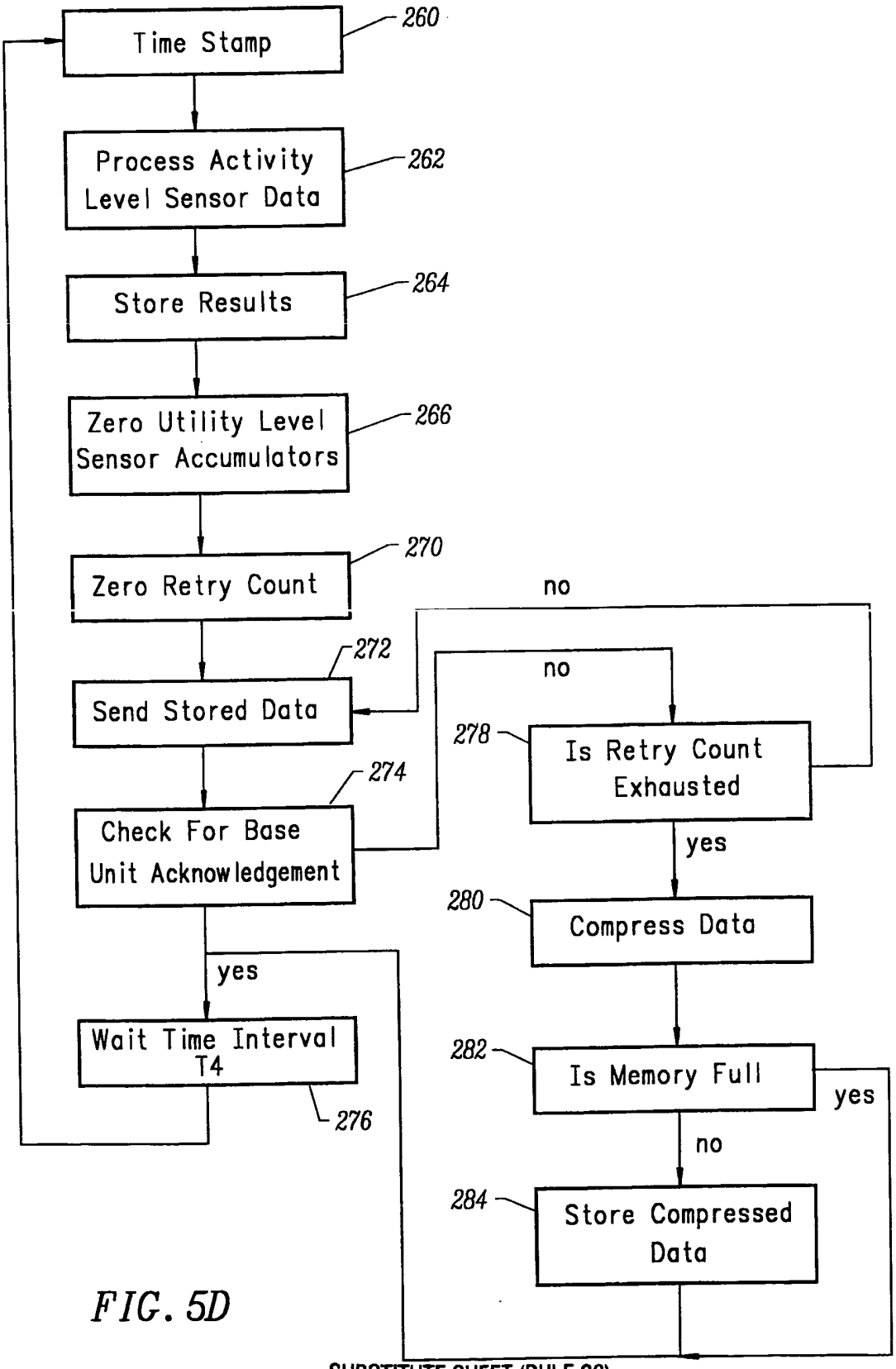
Time Stamp
260
Process Activity Level Sensor Data
262
Store Results
264
Zero Utility Level Sensor Accumulators
266
Zero Retry Count
270
no
Send Stored Data
272
no
278
Is Retry Count Exhausted
Check For Base Unit Acknowledgement
274
yes
280
Compress Data
yes
Wait Time Interval T4
276
282
Is Memory Full
yes
no
284
Store Compressed Data

FIG. 5D

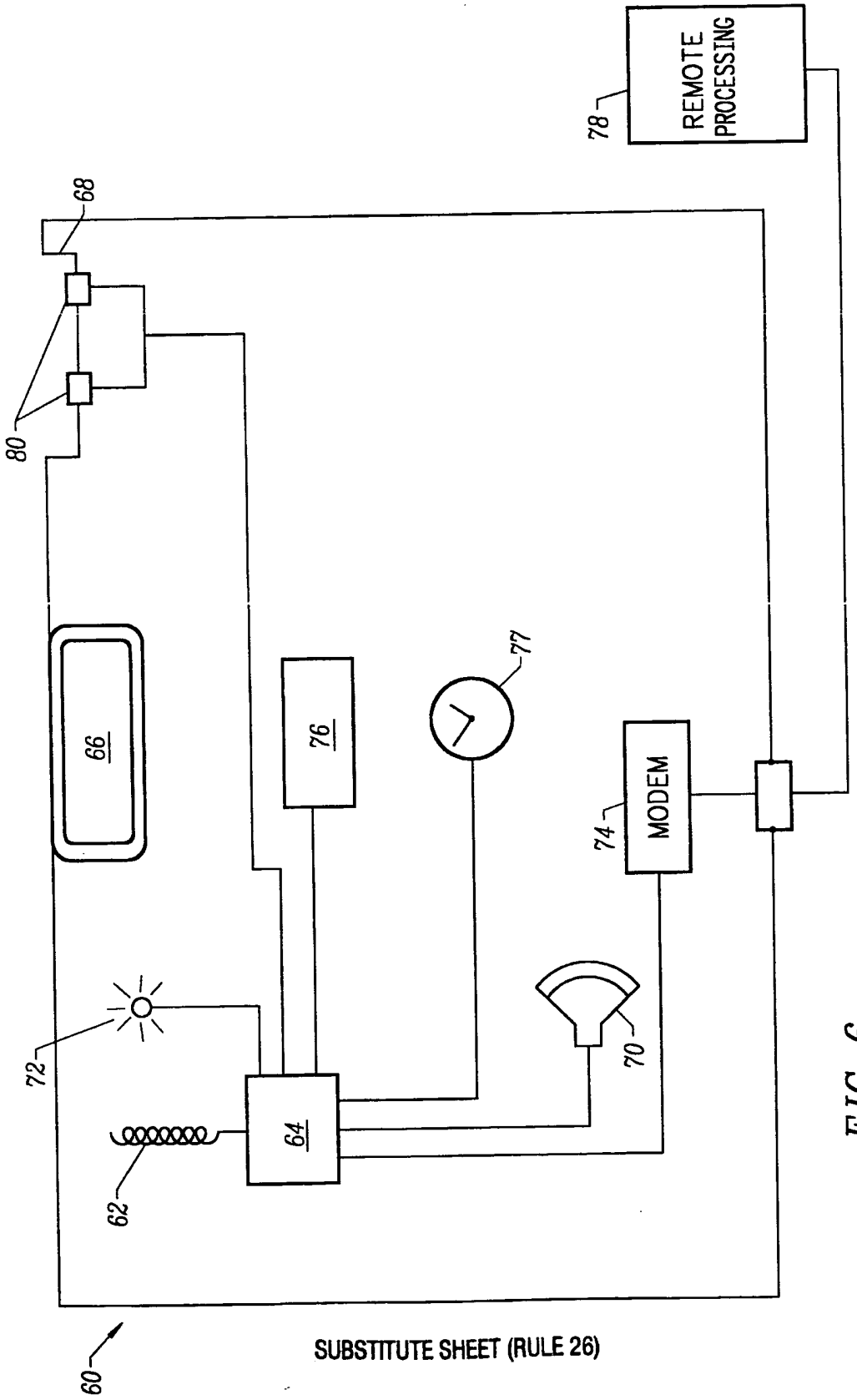

FIG. 6

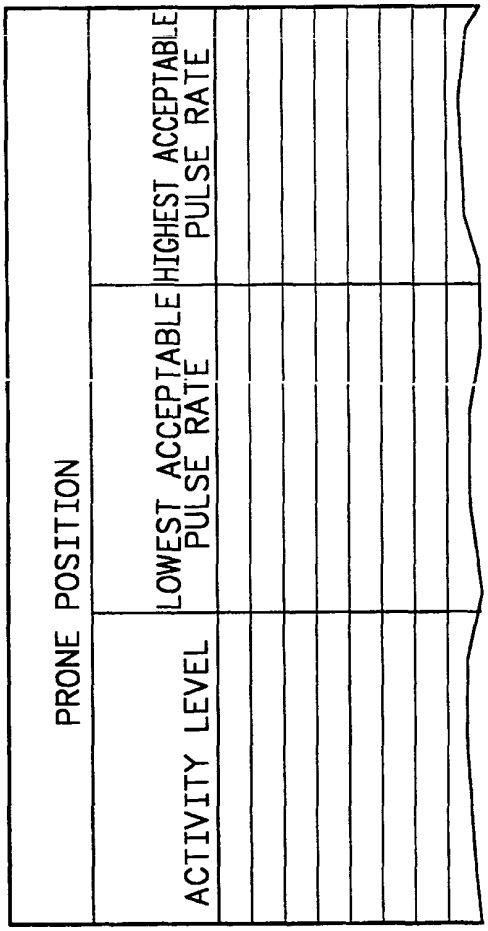
PRONE POSITION
ACTIVITY LEVEL
LOWEST ACCEPTABLE PULSE RATE
HIGHEST ACCEPTABLE PULSE RATE

FIG. 7

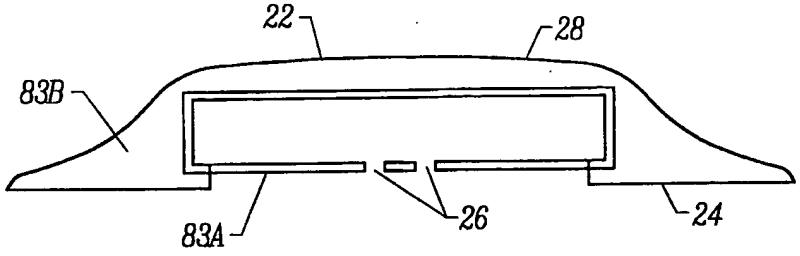

FIG. 8

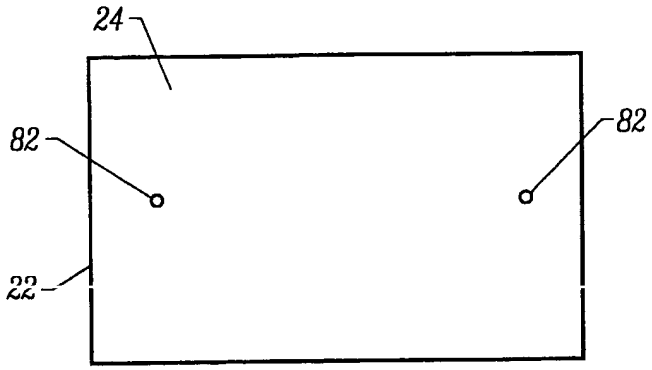

FIG. 9

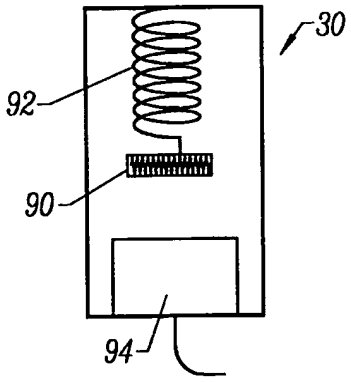

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/06319

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 05/00
US CL :600/500
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/485, 500, 503

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,515,858 A (MYLLYMAKI) 14 MAY 1996, ENTIRE DOCUMENT.	1-32
A	US 5,417,222 A (DEMPSEY ET AL) 23 MAY 1995, ENTIRE DOCUMENT.	1-37
A	US 5,228,449 A (CHRIST ET AL) 20 JULY 1993, ENTIRE DOCUMENT.	1-37

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 17 JULY 1998	Date of mailing of the international search report 30 JUL 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer ROBERT L. NASSER, JR. Telephone No. (703) 308-3251

Form PCT/ISA/210 (second sheet)(July 1992)*